Department of Health and Human Services
National Institutes of Health
National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID), part of the world-renowned National Institutes of Health (NIH), conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. NIAID's Vaccine Research Center (VRC) has the following scientific opportunity available:

Staff Scientist – Director of Analytical Development

The incumbent will direct the analytical development group of the Vaccine Production Program Laboratory (VPPL) in the VRC, which includes the development of assays for release and characterization of recombinant proteins, plasmid DNA, virus vectors, and virus-like particles that could be used as clinical vaccine candidates. The director's primary responsibilities will be to plan the overall scientific and management strategies for assay design, optimization, and delivery to the pilot plant for qualification and clinical material testing to meet project timelines.

Analytical development responsibility includes developing all required product release and characterization assays. The director will work closely with the pilot plant quality control and analytical development groups to transfer assay methods to them and will assist in resolving issues pertaining to assays. Additionally, the director will write and review technical protocols and reports documenting analytical development studies pertaining to the group's work.

The director will also manage an assay services group dedicated to providing analytical testing to upstream and downstream process development groups within VPPL. The director must supervise biochemists, chemists, and engineers at the B.S./M.S./Ph.D. levels. This position requires close coordination with other team members, as most projects require significant teamwork. Therefore, the candidate must be a team player who can work effectively with other research, development, and GMP personnel.

Requirements

Ph.D. in biology, biochemistry, or related discipline with a minimum of 12 years' assay development experience, as well as demonstrated experience developing, qualifying, and validating multiple assays for clinical trials, are required. The candidate must have a thorough knowledge of current GMP, a working knowledge of regulatory guidance documents, and the ability to write investigational new drug and regulatory discussion documents.

The candidate must have expertise in developing assays for well-characterized biologic products such as recombinant proteins. This will include biological (cell-based) potency assays, ELISA, SDS-PAGE and Western blots, IEF/cIEF, CE, FTIR, CD, RP-HPLC, SE-HPLC, mass spectrometry, PCR, host cell protein, and host cell DNA analysis. Experience developing assays

for plasmid DNA, viruses, and virus-like particles is highly beneficial. Experience with assay automation is also highly beneficial.

Confident oral and written communication skills are needed, particularly in writing and reviewing standard operating procedures, quality control data packets, and other testing documents. Familiarity with computer software including word processing and data evaluation is required, as is experience with statistical design of experiments.

Interested candidates may contact Dr. Richard Schwartz, chief of the VPPL, at 301-594-8485 or schwartzri@mail.nih.gov for additional information about the position.

To apply, submit a curriculum vitae, a bibliography, names of three references, a statement of clinical research interests, and reprints of up to three selected publications to National Institute of Allergy and Infectious Diseases, Dale and Betty Bumpers Vaccine Research Center, Office of the Chief, Attn: Dr. Richard Schwartz, Building 40, Room 5502, Convent Drive, Bethesda, MD 20892-3015.

For further information about NIAID and other available career opportunities, visit us on the Web at **www.niaid.nih.gov/careers/ssda.**

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